REMARKS

Claims 3-7, 9 and 11-51 are currently pending in the application. Claims 1-2, 8 and 10 have been canceled. Claims 3-4, 9, 11, 38, 42, 46 and 49-50 have been amended. Claims 3, 4, 38 and 50 have been amended to reflect the relationship between the length of the implantable device from its proximal tail to the distal end such that when implanted, the distal end will not be exposed at the opposite side of the tissue. Claim 49 has been amended to reflect the method practiced in the use of applicants' invention in which the implant is inserted to a depth such that the distal portion is enclosed by the tissue.

APPLICANTS' INVENTION

Applicants' invention is directed to devices and methods relating to tissue implants, such as implants adapted to promote transmyocardial revascularization (TMR). In particular, applicants' invention relates to improvements in such devices for anchoring the implants within the tissue. The anchoring systems are designed to resist migration of the implant that otherwise might lead to ejection of the device from the tissue. The risk of migration is particularly problematic in muscle tissue, such as the myocardium, that exhibits large, regular contractions.

Applicants' invention is directed to TMR implant devices configured to stimulate TMR by evoking a tissue response to the presence of the implanted device rather than by forming a channel to direct the flow of blood from the heart chamber into the heart wall. Applicants' invention is configured so that the distal ends of the device inserted into the tissue will not be exposed or protrude out of the other side of the tissue. The distal portion of the devices are effectively fully enclosed within the tissue and do not provide a lumen accessible through the distal end of the implant. These implants are provided with various means for resisting migration.

THE CITED ART

U.S. Pat. No. 5,810,836 to Hussein *et al.* ("Hussein")

Hussein discloses several TMR devices, each of which is configured so that it can be placed through the myocardial wall to extend fully through the wall and define a flow channel from an interior chamber of the heart. In particular, the Hussein device "...provides a conduit

for the flow of blood nutrients from the ventricular chamber to the intramyocardial vascular network." (2:20-22). Among the disclosed devices is that in FIG. 5 which is said to show "...a flexible stent having a coil body 26 and an anchoring coil 27 which is an integral part of the stent. The anchoring coil prevents detachment of the stent from the heart wall." (3:37-39). There is no explanation of how the "coil 27" prevents detachment. Each embodiment in Hussein appears to include some form of element (anchoring wire 65 in FIG. 1, closure 5 in FIG. 2, closure 12 in FIG. 3, anchor 18 in FIG. 4, anchoring coil in FIG. 27 and an unidentified element in FIG. 6). Each of those elements at the proximal end appears to rest against the external surface of the myocardium with the distal end of the stent being exposed to the interior of the ventricular chamber so that blood can carry nutrients from the ventricle into the myocardial tissue. Among the objectives of the Hussein device is to maintain a patent flow channel for such blood flow. The Hussein device is implanted with the use of a sharp obturator on which the stent is mounted. The obturator pierces the heart wall and is advanced until it pierces the endocardiac surface sufficiently to place the distal end of the device in communication with the ventricular cavity. (see FIG. 7). The obturator then is removed leaving a flow path from the heart cavity into the implanted stent.

U.S. Pat. No. 5,536,274 to Neuss ("Neuss")

Neuss discloses a device for placement within an existing body lumen, such as a blood vessel, for the purpose of occluding the blood vessel. Various coil configurations are disclosed, which serve to restrict flow when implanted in the lumen. FIG. 5 shows a device where the coils progressively increase in diameter from one end to the other. The device is constructed to have a primary shape which will obstruct the lumen, and an elongate, slender secondary shape by which it can be advanced through a tubular guide catheter 16 to the intended placement position in the lumen. The device is configured so that when it is projected out of the tubular guide into the vessel, it will expand to its primary lumen-occluding shape. The device is connected to a guidewire that enables retraction of the device into the distal end of the guide catheter 16 if it is not in the desired deployment position. Alternately, when the device is in the intended deployment position, means are provided to separate the guidewire from the implant, to leave the implant in its obstructed position within the lumen.

U.S. Pat. No. 5,893,869 to Barnhart *et al.* ("Barnhart")

Barnhart discloses a catheter and filter arrangement for temporarily filtering emboli in a blood vessel, namely, the vena cava. The filter does not remain in the vena cava after the device has been used as intended. The system includes a delivery catheter with two lumens, one of which contains a wire that can be projected beyond the distal end of the catheter to define a frusto-conical filter. The deployed filter aligns with the distal opening of the other lumen of the catheter to enable that lumen to be used to aspirate, from the filter, trapped emboli. When the temporary filtering function has been completed, the filter is withdrawn by "...some combination of advancing catheter 31 and withdrawing filter 10...to pull filtering element 14 back into filter deployment/retrieval lumen 36." (6:38-42). The filter remains associated with the catheter at all times.

The distal end of the Barnhart filter terminates in a loop "which creates a blunt surface" so that when deployed, "the looped distal end 27 of filtering element 14 is much less likely to snag, erode or perforate the vena cava wall as opposed to an un-looped wire end." (col. 4, lines 21-26). "Loop 27 at the distal end of the filtering element 14 presents only a blunt surface which helps avoid an otherwise pointed distal end of the wire from eroding or puncturing the vessel wall." (col. 5, lines 63-66).

U.S. Pat. No. 4,130,904 to Whalen ("Whalen")

Whalen discloses a prosthetic blood conduit made of a coil sandwiched between two polyester fabric tubes. Fig. 2 shows the very end of the coil as being affixed to the previous coil to form a closed ring, "thereby avoiding interference by the free end 30 within living tissue." (col. 2, lines 41-45).

U.S. Pat. No. 5,484,424 to Cottenceau *et al.* ("Cottenceau")

Cottenceau discloses a catheter with a blood filter attached to one end. Springs are illustrated in Figs. 13 and 14 and are referred to at col. 5, lines 25-26 as being incorporated into the catheter walls to stiffen it. The springs exist only within the catheter and remain within it.

CLAIM REJECTIONS

Claim Rejections Under 35 U.S.C. § 102

Reconsideration is requested of the rejection of claim 49 as anticipated by Hussein. Claim 49 has been amended to specify that the method includes insertion of the device to a depth such that the distal portion of the device is enclosed by the tissue in which it is implanted. With applicants' invention, the transmyocardial revascularization is not effected by creating a channel in the myocardium to enable blood to flow from the ventricle into the myocardial wall, as is essential in each of the Hussein embodiments. With applicants' claimed method, the device is inserted only to a depth such that the distal portion is enclosed by the tissue. Hussein does not disclose such a method and, indeed, such a method would be directly contrary to Hussein's objective. Additionally, there is nothing in Hussein to disclose that the flexibility of the implant serves to observe the migratory forces applied on the device after implantation. To the extent that Hussein may disclose any anchoring function, that appears to relate, somehow to the elements on the proximal end of the device, not to characteristics relating to the longitudinal flexibility of the device.

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claims 3-7, 9, 13-15, 18-24, 30-37 and 50-51 as unpatentable in view of the combined disclosures of Neuss, Hussein and Barnhart. Reconsideration of the rejection of these claims is requested first, because the combination of Neuss, Hussein and Barnhart is improper and second, even if somehow, combined they would not have suggested applicants' claimed invention.

Of Neuss, Hussein and Barnhart, only Hussein relates generally to the subject matter of applicants' invention, to a device adapted to be implanted in tissue. Neuss and Barnhart relate to various coil-like devices intended to be deployed within an existing body lumen in engagement with the luminal surface of the vessel. Neither Neuss nor Barnhart relates to a device intended to be implanted in tissue. Moreover, Neuss relates to a device that is intended to be placed and left within a blood vessel to occlude the blood vessel. Barnhart is a temporary device adapted to be placed in the lumen of the vena cava for a limited period of time sufficient to filter out emboli in the blood. None of Neuss, Hussein and Barnhart suggest any reason for combining them in any

manner, much less in the manner claimed by applicants. Each of those references is directed to a different objective and each functions differently. There is no evidence identified in the official action of any motivation for combining any of Neuss, Hussein and Barnhart in any manner. The combination is improper.

Whether or not disclosures in two or more prior art references are properly combinable depends, generally, on whether there is some teaching or suggestion in those references or elsewhere in the prior art to suggest the desirability of making the combination. The mere fact that it is possible to find two isolated disclosures having some individual features that might be combined in a manner that would result in the claimed invention is not enough. There must be something in the prior art itself that suggests the desirability of that claimed combination. It is improper to pick and choose among the individual parts of various prior art references as a mosaic to recreate a facsimile of the claimed invention using the inventor's disclosure as an instruction book on how to reconstruct the prior art. To do so is impermissible hindsight reasoning. Additionally, the problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in that manner to solve a particular problem. *See In Re Fine*, 5 USPQ2d 1596,1599 (Fed. Cir. 1998).

Each of independent claims 3 and 4 has been amended to recite that the implant length is less than that of the wall thickness of the myocardium whereby, when implanted, the distal portion will be disposed proximally of the innermost surface of the myocardium and the tail will be disposed, at least in part, below the external surface of the myocardium. Hussein discloses neither of those features. In Hussein, the distal end of the implant necessarily must extend so as to be exposed to the ventricle. Additionally, there is nothing in Hussein to disclose a device having a tail adapted to be disposed below the external surface of the myocardium when the device is implanted with its distal portion proximally of the innermost surface of the myocardium. Even if Neuss or Barnhart were properly combinable (which they are not) with Hussein, neither of them can be considered as suggesting that Hussein should be modified to include these features of applicants' invention. The rejection of claims 3 and 4, and the claims dependent therefrom, necessarily is based on hindsight reasoning and is improper.

As to the tail, the action mailed January 20, 2004 asserts (at page 9, lines 7-10) that Fig. 8I of Hussein shows a device having a tail "submerged below the surface of the tissue after

implantation," but the device in the cited figure is too small to show the tail below the surface of the tissue. Section 2125 of the Manual of Patent Examining Procedure discusses the use of drawings as prior art, and states that "[d]rawings and pictures can anticipate claims if they clearly show the structure which is claimed. . . . However, the picture must show all the claimed structural features and how they are put together." In addition, "[t]he drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art." *Id.* References must be evaluated by ascertaining the facts fairly disclosed therein as a whole. *In re Meng*, 492 F.2d, 843, 181 U.S.P.Q. 94 (C.C.P.A. 1974), citing *In re Shuman*, 53 C.C.P.A. 1251, 361 F.2d 1008, 150 U.S.P.Q. 54, 57 (C.C.P.A. 1966).

The device in Fig. 8I of Hussein is too small to clearly show the tail below the surface of the tissue. All of the figures in Hussein which show the tails of the devices clearly (Figs. 1-4 and 6-7), show the tails on the surface of the tissue, not submerged beneath it. This is in direct contrast to the tails of the devices of claims 38-48, and the description in applicants' specification at page 3, line 20 to page 4, line 2, page 4, lines 13-25, and Figs. 1 and 5. Applicants respectfully request that the rejection on this basis be reconsidered and withdrawn.

Claim 50 has been amended in a manner similar to claims 3 and 4 except that it refers to the tail merely as being "in engagement" with the outer surface of the myocardium when the distal portion is fully enclosed by the myocardium. Even if Hussein were, somehow, combined with one or both of Neuss and Barnhart, there is nothing in either of those references to suggest that Hussein should be modified in the manner claimed.

Each of claims 11 and 12 depends directly or indirectly from claim 3 and is patentable for the same reasons. Additionally, neither Neuss nor Hussein discloses devices associated with surgical adhesive, as required by amended claim 11.

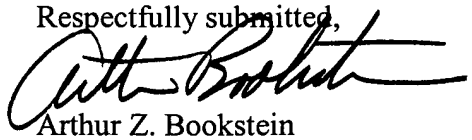
Reconsideration is requested of the rejection of claims 16 and 17 as unpatentable under 35 U.S.C §103 in view of the combined disclosures of Neuss, Hussein, Barnhart and Cottenceau. Claims 16 and 17 ultimately depend from claim 50 and are patentable for the same reasons discussed above in connection with claim 50. Cottenceau discloses an intraluminal filtration device that includes a tubular shaft reinforced by a helical coil having varying flexibility. There is no evidence of any motivation to combine any aspect of Cottenceau with any of Neuss, Hussein or

Barnhart. Moreover, even if somehow they were combined, there is nothing to suggest those features of claims 16 and 17 that are missing from each of Neuss, Hussein and Barnhart.

Reconsideration is requested of the rejection of claims 25-29 as unpatentable under 35 U.S.C. §103 in view of the combined disclosures of Neuss, Hussein, Barnhart and Whalen. Whalen is directed to a prosthetic blood vessel. Each of claims 25-29 depends, ultimately, from claim 4 and is patentable for the same reasons. Whalen is directed to artificial blood vessels, not to devices adapted to be implanted within tissue and certainly not to transmyocardial revascularization devices. Whalen fails to suggest those features of applicants' invention that are missing from Neuss, Hussein and Barnhart. In addition to being an improper combination of references, there is no basis on which Whelan can be considered as suggesting the modification of any of Neuss, Hussein and Barnhart in any manner, much less in the manner at claimed.

Reconsideration is requested of the rejection of claims 38-48 as unpatentable under 35 U.S.C. §103 in view of the combined disclosures of Hussein and Neuss. The method as claimed in amended claim 38 recites that the length of the implantable device is less than the thickness of the tissue wall whereby the device can be implanted within the wall with at least part of the tail disposed below one surface of the wall and the distal portion of the implant being disposed within the wall and spaced from the opposite surface of the wall. Independent claim 42 has been amended to recite that the implant includes a tail and that the device is inserted so that its distal end is covered by the tissue and the tail is embedded below the tissue surface. For the reasons discussed above, neither Hussein nor Neuss discloses or suggests the claimed method. Indeed, the combination of Hussein and Neuss is improper because they are directed to unrelated procedures and there is no evidence of a reason to suggest their combination.

Respectfully submitted,



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